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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
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June 7, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

01-SWR-WL-53/0

Gregory C. Reed
Hospital CEO/Administrator
Pike County Memorial Hospital
2305 West Georgia
Louisiana, MO 63353

RE: Inspection ID - 2083550006

Dear Gregory C. Reed,

On June 1, 2001, a representative of the State of Missouri acting in behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

The Mammography Quality Standards Act of 1992 requires your facility to meet specific standards. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and repeated level 2 findings at your facility:

Level 1: Phantom QC records were missing for at least 4 weeks for unit 2, Bennett X-Ray Corp.

Level 1: Failed to produce documents verifying that the interpreting physician [redacted] MD met the initial requirement of holding a valid state license to practice medicine.

Level 1: Failed to produce documents verifying that the interpreting physician [redacted], MD met the initial requirement of holding a valid state license to practice medicine.

Level 1: Failed to produce documents verifying that the interpreting physician [redacted], MD met the initial requirement of holding a valid state license to practice medicine.

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Level 1: Failed to produce documents verifying that the interpreting physician [redacted], MD met the initial requirement of holding a valid state license to practice medicine.

Level 2 repeat: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, Bennett X-Ray Corp.

Level 2 repeat: Failed to produce documents verifying that the radiologic technologist [redacted] (12 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.

Level 2 repeat: 2 of 10 random reports reviewed did not contain an acceptable assessment category.

[A finding is considered a repeat finding if the same type of violation was cited during the previous inspection, whether or not the finding is associated with the same piece of equipment (x-ray unit, processor, or darkroom) or the same personnel in a given category.]

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Level 1 and repeated level 2 findings may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. They represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to:

- Placing your facility under a Directed Plan of Correction.
- Charging your facility for the cost of on-site monitoring.
- Assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the level 2 findings that were listed on the inspection report provided to you at the close of the inspection. The inspection revealed the following level 2 findings:

Level 2: The facility has not specified adequate procedures to be followed for infection control or did not follow them when required.

Level 2: Corrective actions for processor QC failures were not documented at least once for processor 1, Kodak.

Level 2: Medical audit and outcome analysis was not done for the facility as a whole.

Level 2: There were no examples of, nor attempts, to get biopsy results.

Level 2: Medical audit and outcome analysis was not done separately for each individual.

Level 2: Medical audit and outcome analysis was not performed annually.

It is necessary for you to act on this matter immediately. You are required to respond to this office in writing within fifteen (15) working days from receipt of this letter. Please address the following:

- The specific steps you have taken to correct all of the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate.
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:
Deborah M. McGee, Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982

This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 ext. 138.

Sincerely yours,

Gary L. Pierce
Regional Food and Drug Director